AC Contract Manufacturing: Change Control for HPC(A) and MNC(A)

Amy E. Hines BSN, RN, CHTC - Be The Match BioTherapies
Jody McNaughton - NMDP / Be The Match
Katherine St. Martin, MS, RAC(US) – NMDP / Be The Match

Disclosures

The following faculty and planning committee staff have no financial disclosures:

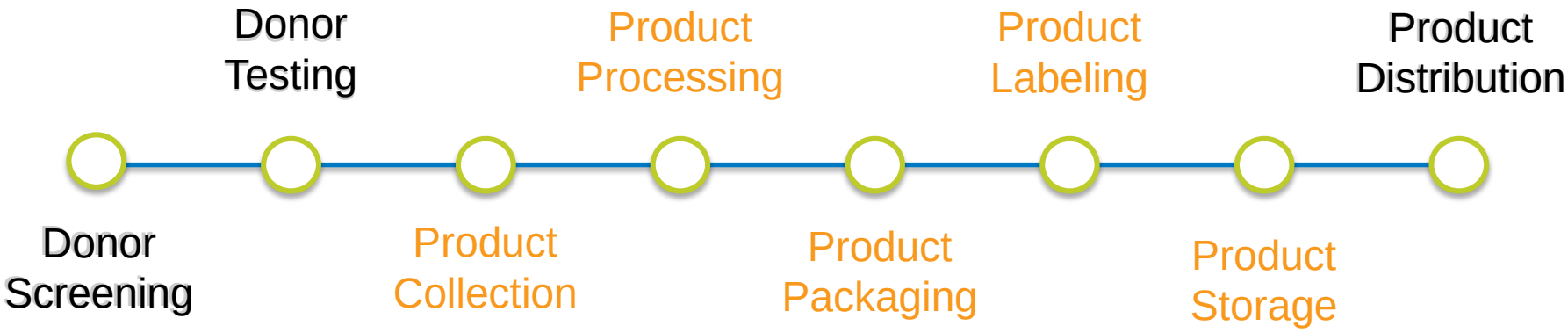
Name	Institution
Amy E. Hines	Be The Match BioTherapies
Jody McNaughton	NMDP / Be The Match
Katherine St. Martin	NMDP / Be The Match
Ruth Bakken	NMDP / Be The Match
Jami Chapman	NMDP / Be The Match
Bette Braem	NMDP / Be The Match

Learning objectives

At the conclusion of this session, attendees will be able to:

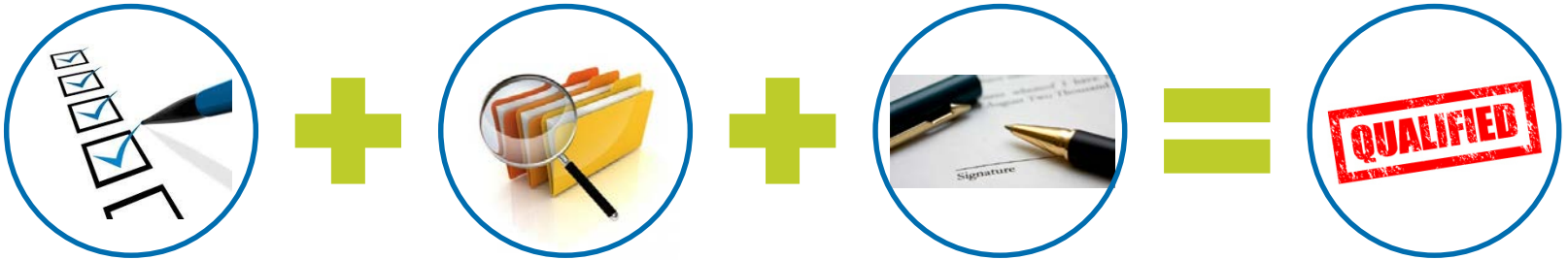
- List the main components of the NMDP AC Change Control process
- State the rationale for why NMDP is initiating a Change Control process as part of AC qualification

What is AC Contract Manufacturing **Qualification**?



Process for retroactively qualifying existing ACs and ensuring ACs continually meet FDA requirements for the manufacturing of HPC(A) and MNC(A)

Initial Qualification Process



Supplier Questionnaire

Onsite Audit

Qualification Review

AC Contract Manufacturing Status

FY	Supplier Questionnaire	Audit	Qualified
FY16	9	9	8/9
FY17	All centers	15	8/15

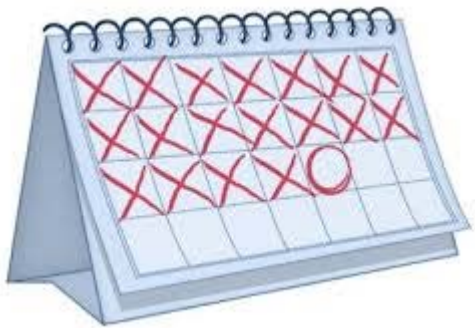
Timeline

Complete qualifications by mid-2020

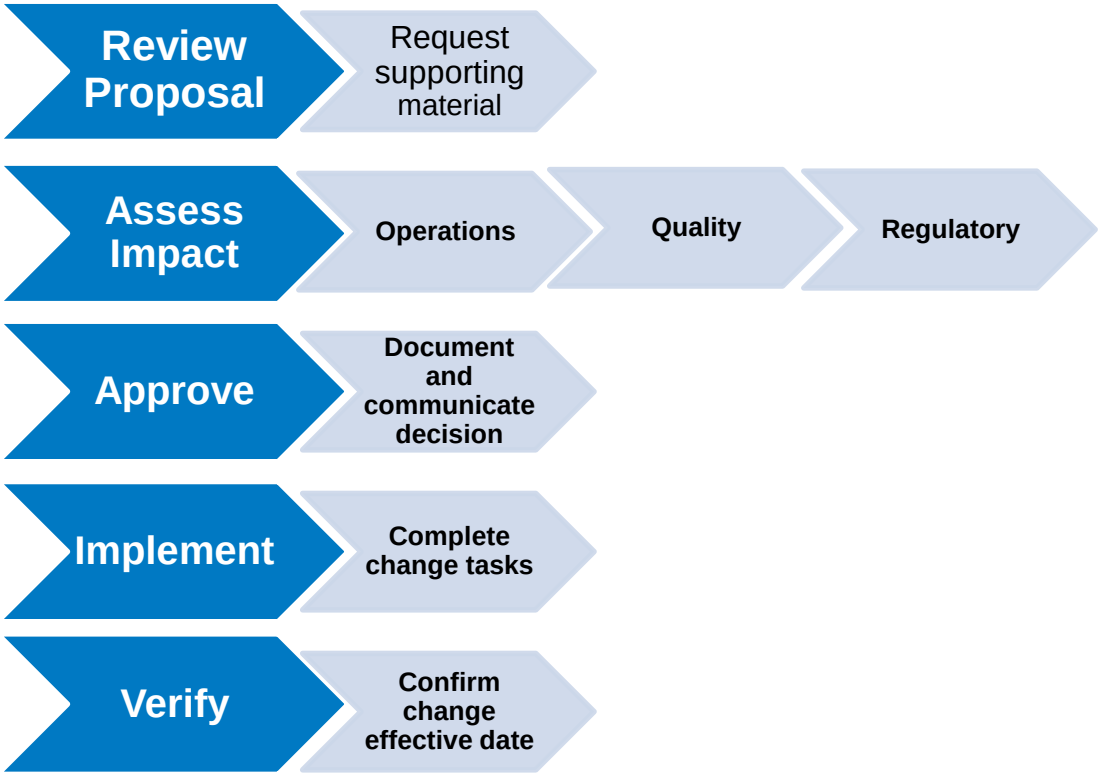
2016 ✓ 9 ACs — 2017 ✓ ~20 ACs — 2018 ~20 ACs — 2019 ~20 ACs — 2020 ~20 ACs — 2021

Change Control = Planned Changes

- Change control is a well-known manufacturing concept that focuses on managing change to prevent unintended consequences
- Change Control is industry best practice:
  - ICH Q10: Pharmaceutical Quality System
- It's also a core GTP/GMP requirement:
  - 21 CFR 1271.160(a): Quality Program
  - 21 CFR 1271.225: Process changes
  - 21 CFR 211.22: Quality Control Unit



NMDP Change Control Process



NMDP Change Control Process

- Integrated - Electronic process flow that integrates with document management, incident management and other quality processes
- Visible – Participants can track changes through process
- Capture Assessments – Impact assessments built into process
- Provides flexibility to add appropriate assessor
- Decisions – Way to document decisions and add supporting communication within process
- Risk – Change types are defined by FDA based on potential impact on product SQUIPP and incorporated into electronic process
- Reports – Able to produce reports of changes in process, overdue, closed, etc.

Survey Results Discussion

NMDP AC Change Control Process

Evaluate potential risk to product or process

+

Discuss impacted areas

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NEW

Notify NMDP through web-based form *

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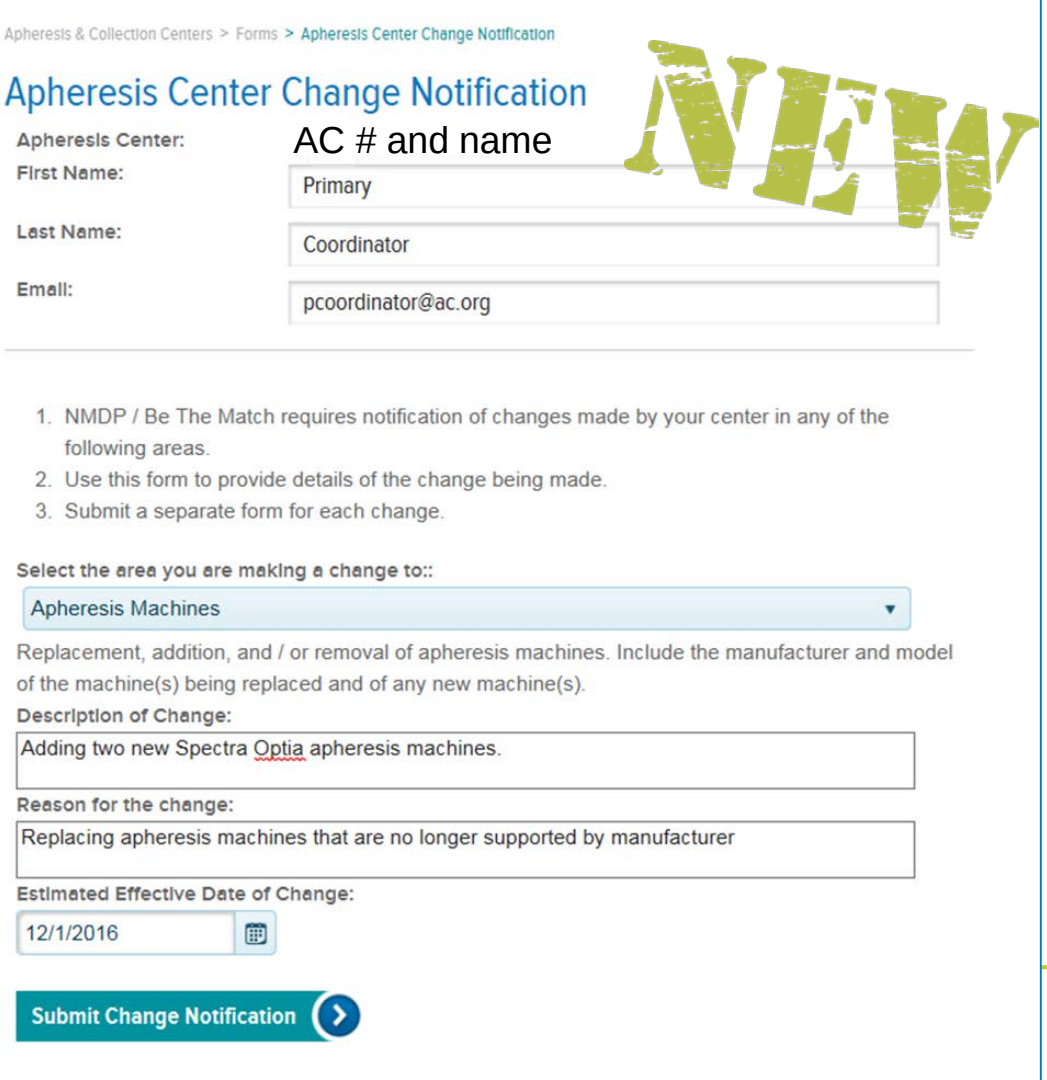
Implement



When do I need to submit it?

Changes to/notifications about:

- Apheresis machine(s)
- Final labeling method
- Accreditation status
- FDA notification
- Central line provider
- Recalls impacting SQuIPP

Deviations = Unplanned Changes

- Core Business Deviations
  - Real time Notification: Call the AC/CC Liaison Team
  - Allows the Transplant Center to stay informed, make adjustments

- New Business Development Deviations
  - Real time Notification: Call the BTMB AC Liaison Team
  - Determination of whether to collect; no patient awaiting the product

Complaints, CAPA = Quality Incidents

- A problem, nonconformance, event or deviation that has adversely affected or has the potential to adversely affect manufacturing of an HPC product, patient or donor safety, confidentiality or compliance with NMDP Standards

References

- Contact Information:
  - AC_Contract_Manufact@NMDP.org
- Change Notification Form:
  - https://network.bethematchclinical.org/My-Account/Apheresis-Center-Change-Notification/

Evaluation Reminder

Please complete the Council Meeting 2017 evaluation in order to receive continuing education credits and to provide suggestions for future topics.

We appreciate your feedback!